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Plaintiffs' counsel

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

I.C. and I.D.

Plaintiffs,

v.

CHART INC.

Defendant.

Case No.

COMPLAINT AND DEMAND FOR JURY TRIAL

INTRODUCTION

1. On March 4, 2018, during a walkthrough of a laboratory at the Pacific Fertility Center, an embryologist discovered the lid of one of the cryopreservation tanks was stuck in place and condensation had pooled on the floor. That tank contained 2,500 embryos and 1,500 eggs from patients who had undergone egg-retrieval or IVF procedures.

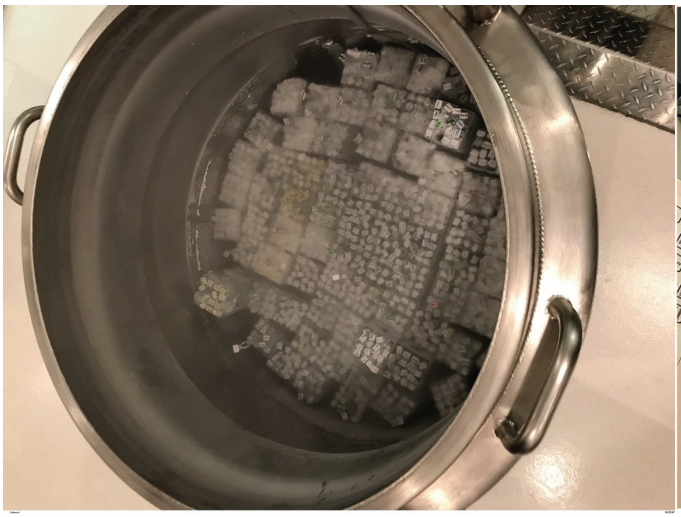
2. The embryologist immediately recognized something had gone seriously wrong. Much like a thermos, cryopreservation tanks depend on a vacuum layer to insulate frozen eggs and embryos—which are stored in a bath of liquid nitrogen at -198° C—from the much warmer, room-temperature laboratory. The condensation was a sign the vacuum had failed and the tank was warming—endangering the previously frozen eggs and embryos.

3. The embryologists at PFC worked quickly to transfer the eggs and embryos to another tank and later alerted the affected patients, which included Plaintiffs. At the time of this widely publicized incident, PFC could not say why its cryopreservation tank had failed so suddenly or how much the eggs and embryos stored inside would be affected.

4. Expert analysis of the tank conducted since the incident has revealed that the tank failed due to a defective weld near the bottom of the tank. The weld was too thin and the fit between the welded portions of the tank was improper. As a result, the weld was unable to withstand long-term exposure to normal thermal stresses and eventually cracked. When it did, the tank immediately lost its vacuum insulation and ability to maintain a safe temperature for the PFC patients' eggs and embryos.

5. The cracked weld also triggered an implosion of the tank's inner vessel, as the liquid nitrogen that was sucked into the vacuum space transitioned to gaseous nitrogen and exerted pressure

on the inner vessel's walls. That is why the lid of the tank was difficult for PFC's embryologists to remove. The imploded tank is shown below, on the right:



Normal Tank

Imploded Tank

6. This dramatic result is exactly what the tank's manufacturer, Defendant Chart Inc., predicted would occur if the weld were to crack, but Chart has so far failed to take responsibility for the tank failure.

7. Expert analysis conducted since the tank failure has, unfortunately, also confirmed that the vast majority of the frozen eggs and embryos stored inside when the weld cracked are no longer viable. Many PFC patients are understandably reluctant to attempt IVF with eggs or embryos that have been subjected to dangerous conditions. But when patients do try, they rarely succeed. Less than 6% of attempts have resulted in live births.

8. Under California products liability law, Defendant Chart is strictly liable for the harm resulting from its defective weld. Chart manufactures critically important cryopreservation tanks that PFC and its patients depended on to keep their eggs and embryos safe. The company has profited considerably from its sale of cryopreservation equipment and is required to bear the societal cost when that equipment turns out to be defective.

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction under 28 U.S.C. § 1332(a)(1) because Plaintiffs and Chart are citizens of different states and the amount in controversy exceeds $75,000.

10. Venue is proper in this District under 28 U.S.C. § 1391 because Chart resides in this district and a substantial part of the events or omissions giving rise to this action occurred in this district. The cryopreservation tank at issue in this litigation was located in San Francisco when it failed, resulting in damage to Plaintiffs.

INTRADISTRICT ASSIGNMENT

11. Assignment to the San Francisco or Oakland Division is proper under Local Rules 3-2(c) and (d) because a substantial part of the events or omissions giving rise to Plaintiffs' claims occurred in San Francisco.

PARTIES

12. Plaintiffs I.C. and I.D. are citizens and residents of Alameda County, CA. Given the sensitive nature of this litigation, Plaintiffs and other PFC patients filing suit against Defendant Chart are using randomized initials to protect their privacy.

13. Defendant Chart Inc. is a Delaware corporation headquartered in Ball Ground, Georgia. Chart is a wholly owned subsidiary of Chart Industries, Inc., a publicly traded company with a market capitalization of $1.9 billion. Chart Industries describes itself as "a recognized global brand for the design and manufacture of highly engineered cryogenic equipment."

FACTUAL ALLEGATIONS

I. Tank 4: A Chart MVE Cryopreservation Tank

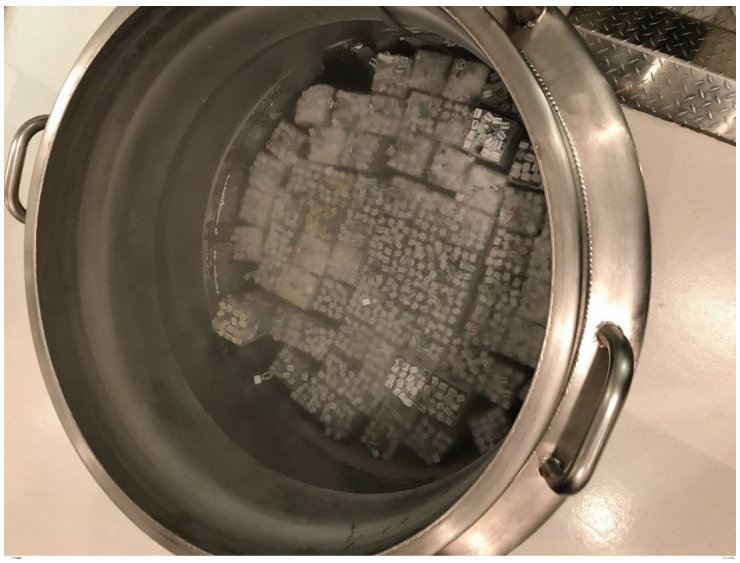
14. Defendant Chart manufactures the MVE brand of cryogenic containers, which it markets to hospitals and clinics for the storage of highly sensitive human tissues, including eggs and embryos. According to Chart, "[t]he MVE brand is your guarantee that products have been engineered for ultimate reliability and maximizing hold times at the ultra-low temperatures vital to securing the stable environment for sample storage."

15. The tank at issue in this litigation is an MVE-branded cryopreservation tank—specifically, a model MVE 808AF-GB Stainless Steel Freezer, which the embryologists at the Pacific Fertility Center referred to as Tank 4:

Tank 4

16. The tank consists of the outer vessel seen above, an inner vessel that can be used to store eggs and embryos in liquid nitrogen, and an insulated vacuum layer that separates the two vessels and prevents heat transfer from the surrounding environment.

17. The tank's inner vessel is shown below:



18. The tank is filled with liquid nitrogen and dozens of boxes, each with further dividers that collectively can house hundreds of slender vitrification devices used to collect each respective egg or embryo.

19. The picture below was taken following failure of Tank 4 and shows the tank's inner vessel (wrapped in reflective material) being removed from the outer vessel. In between the two vessels was an interstitial space. Before a tank is put into service, Chart draws a vacuum within that space by sealing it shut and pumping out the air. The resulting vacuum space is what allows cryopreservation tanks to keep liquid nitrogen and biological samples at -198° C.

Tank 4's inner vessel suspended after removal from outer vessel (vacuum space was in between)

20. Heat transfer occurs when molecules bump into other nearby molecules and transfer some of their energy. Because the tank's vacuum space contains very few molecules, heat transfer from the outside environment to the tank's inner vessel is minimal when the vacuum is intact. Some of the liquid nitrogen gradually warms above -198° C and evaporates, but only a small portion each day, which can be replenished by adding more liquid nitrogen. Without the vacuum space, however, the liquid nitrogen inside the tank quickly warms up, turns into a gas, and leaves the biological samples exposed.

21. Tank 4 should have lasted at least 10 years. That is to say, the tank's vacuum space should have continued to effectively insulate the cryopreserved eggs and embryos inside the tank for at least 10 years. Moreover, even after 10 years, the vacuum should deteriorate slowly, as molecules gradually migrate through the stainless steel and reduce the vacuum's effectiveness—it should not have failed suddenly or without warning.

22. As Chart itself tells customers, continued use of its tanks to store biological materials after 10 years is normal and acceptable.

II. The Defect in Tank 4

23. Tank 4 was only six years old when its vacuum insulation suddenly failed. The reason for the failure was a defective weld near the bottom of the tank's inner vessel.

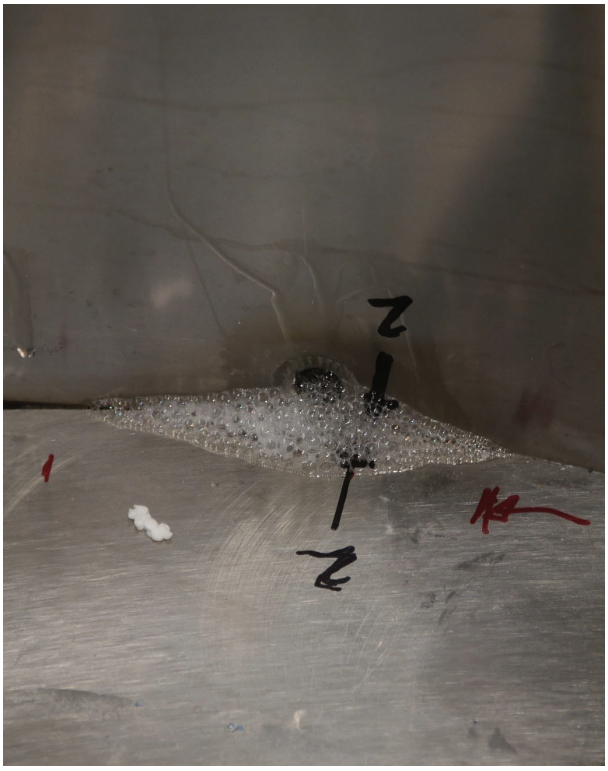
24. Tank 4 was manufactured with a metal tube that is used to refill the tank with liquid nitrogen. The tube ran from the top of the tank, down through the vacuum space between the inner and outer vessel, and then into the inner vessel near the bottom of the tank.

25. The picture below was taken after the outer vessel of Tank 4 was removed. The liquid nitrogen tube is on the left and the red circle shows where it connects to the inner vessel through a fitting.

Liquid nitrogen tube feeds into Tank 4's inner vessel

26. The fitting is held in place by a single weld on the inside of the inner vessel wall. That weld cracked, as shown in the images below. The image on the left was taken after application of Snoop Liquid Leak Detector. The bubbles indicate a leak. After multiple inspections of the tank by all interested parties, including leak testing by Chart, no other leak has been detected.

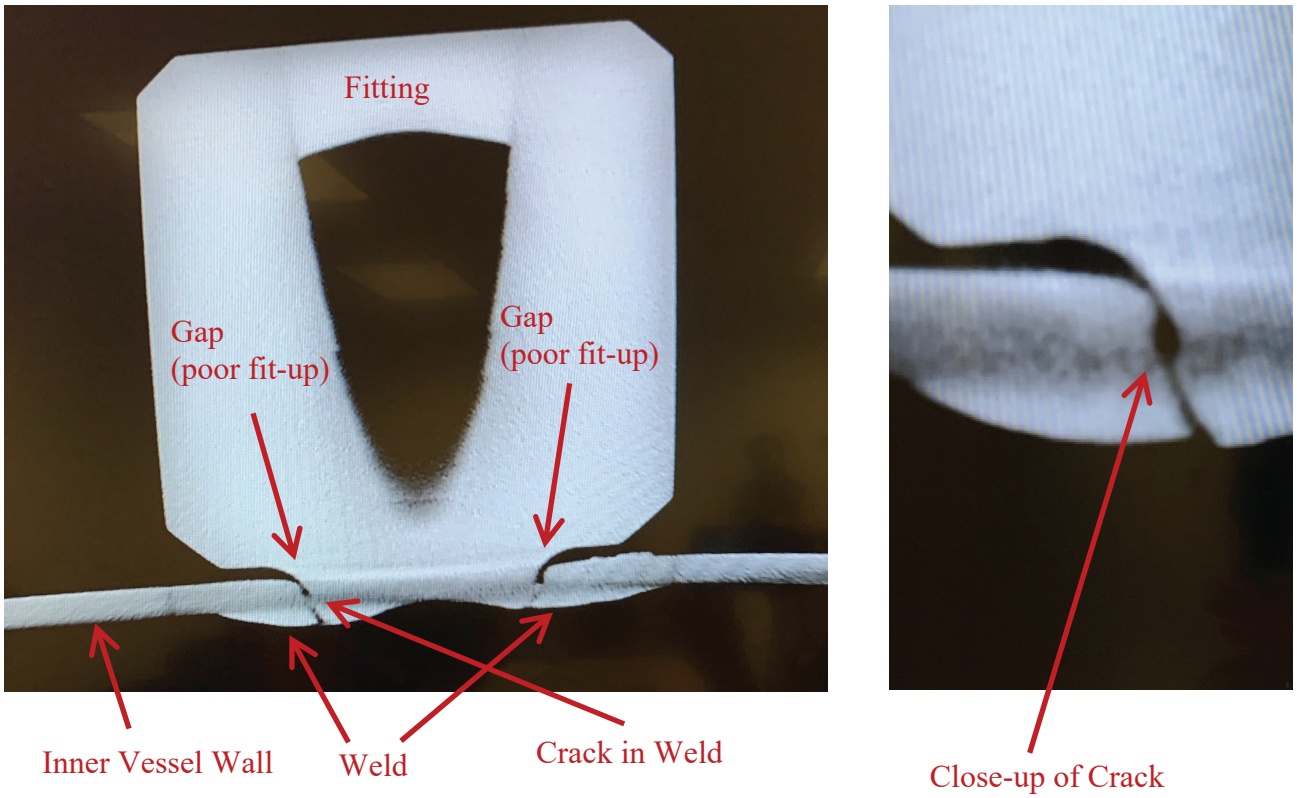
27. The image on the right is the same weld, this time after using Magnaflux Spotcheck liquid dye penetrant. The fact the red dye penetrant remained after the surface was wiped clean is indicative of a crack.



Bubbles indicate a leak

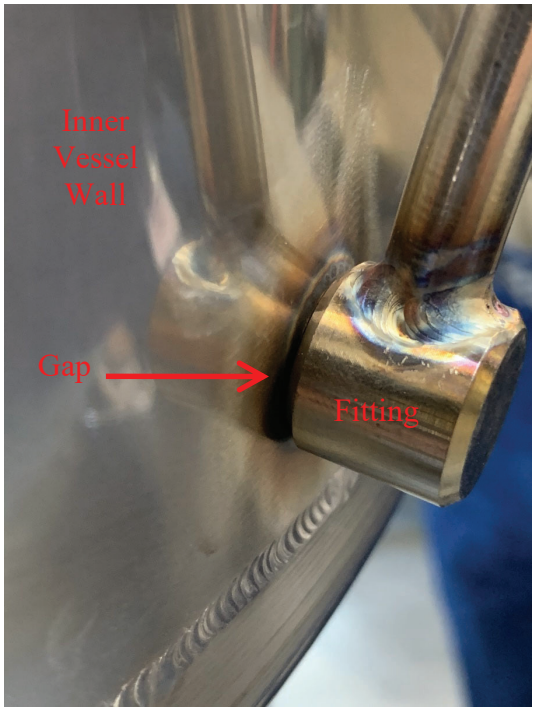
Red dye indicates a crack in the weld

28. The presence of a crack was further verified through CT scans of the weld, shown below. The image on the left is a cross-section where the fitting connects to the tank's inner vessel and the image on the right is a close-up of the weld. The CT images shows a clear crack through the weld.



29. The CT scans also indicate why the weld likely failed. The weld was very thin in the area of the crack—only a fraction of the thickness of the tank wall.

30. In addition, the fit between the inner vessel wall and the fitting was poor. The weld should have fused together the entire edge of the inner vessel and the fitting. But the poor fit left an excessive gap—as shown in the CT image and in a close-up of the fitting below.



31. As a result, the weld was unable to withstand the stresses that occur in normal operation of the tank, such as when liquid nitrogen flows through the tank's fill tube and causes the rapidly cooling metal to constrict and place stress on the weld. Eventually the weld cracked.

32. When the faulty weld cracked, the vacuum space was no longer separated from the inner vessel where PFC kept its patients' eggs and embryos. Liquid nitrogen was sucked into the vacuum space, where it expanded into nitrogen gas and pressurized the space between the inner vessel and outer vessel.

33. The crack and accompanying leak of liquid nitrogen into the interstitial space both destroyed the vacuum insulation that allowed the inner vessel to stay cold and exerted significant pressure on the space between the tank's inner and outer vessel. The inner vessel gave way and crumpled. The following image was taken approximately 36 hours after the PFC embryologists discovered the Tank 4 failure and moved the affected eggs and embryos to another tank.

Tank 4 after the incident

34. This dramatically imploded tank is yet another indication of a cracked failure. As part of its compliance with the European Union's Medical Device Directive, Chart was required to attempt to identify every way that its cryogenic freezers could theoretically fail. Representatives from Chart's various departments came up with over a hundred potential failure modes. One of them was a cracked weld at the liquid nitrogen fill tube—exactly what expert analysis revealed happened to PFC's Tank 4. If that weld did crack, Chart wrote that the result would be: "Liquid draws into vacuum space, expanding rapidly and causing an inner vessel implosion, total vacuum loss. Loss of function of the freezer."

	A	B	C	D	E	F
1	**Design Failure Mode, Effects and Criticality Analysis**					
2	**CRYOGENIC FREEZERS: MVE, HECO, VARIO, CRYOSYSTEM FULL AUTO**					
3	**ID#**	**Item**	**Item Function**	**Potential Design Failure Mode**	**Potential Cause of Design Failure Mode**	**Immed Effect of failure**
47	DEW-3	Dewar- Annular lines	Fill line from the outer to inner vessel	Crack or leak	Weld Line Failure	Liquid draws into vacuum space, expanding rapidly and causing an inner vessel implosion, total vacuum loss. Loss of function of the freezer

Chart's Failure Analysis: Cracked weld would cause a tank implosion

35. The only other failure mode that Chart identified that would lead to an inner vessel implosion also involved a weld crack. Chart has revised its failure analysis many times over the course of several years, including after Tank 4 failed, and has never identified any way that a cryopreservation tank could spontaneously implode other than from a cracked weld.

36. To make matters worse, Tank 4's electronic controller—which monitors liquid nitrogen levels and temperature—malfunctioned shortly before the incident. To the extent this malfunctioning controller contributed to the harm suffered by Plaintiffs, Chart is responsible for that as well. Chart knew its electronic controllers were prone to malfunction—or "spontaneously go haywire," as Chart put it—and estimated it had received a hundred or more complaints from customers about the issue.

37. Chart could have and should have recalled or retrofitted all tanks manufactured with the faulty controller well before Tank 4's weld cracked, but failed to do so.

III. The Damage Caused By Chart's Defective Tank

38. Frozen eggs and embryos are supposed to be thawed extremely quickly—otherwise, harmful ice crystals form, cause intracellular damage, and reduce the likelihood of a successful pregnancy. But Chart's defective cryopreservation tank caused the frozen eggs and embryos stored in Tank 4 to gradually thaw.

39. For those who have attempted to use eggs and embryos from Tank 4, the result has been dramatically lower success rates at every stage of the IVF process. The table below compares PFC's pre-incident success rates (using data for tissue thawed in 2017) versus its post-incident success rates

(using data for Tank 4 tissue thawed after the weld cracked on March 4, 2018). The data is preliminary but the impact is unmistakable: material from Tank 4 is far less likely to produce a thawed egg or embryo viable for transfer and implantation, far less likely to result in a clinical pregnancy, and far less likely to result in a live birth.

IVF Stage	Pre-Incident	Post-Incident
Thaw Success	97%	44%
Clinical Pregnancy	57%	15%
Live Birth	46%	6%

40. For PFC patients who had eggs or embryos stored in Tank 4 this represents a tremendous loss. Fertility patients endured painful and invasive procedures, financial stress, and the strain the process puts on their mental health and relationships with others, all in the hopes that one day they will be able to have a child. To see that opportunity so severely compromised, if not lost completely, has been devastating.

FIRST CAUSE OF ACTION
Strict Products Liability – Manufacturing Defect

41. Chart is strictly liable to Plaintiffs for harm caused by manufacturing defects in Tank 4 under California products liability law.

42. Chart manufactured Tank 4, which contained at least one manufacturing defect when it left Chart's possession. In particular, the weld at the liquid nitrogen fill port, which should have sealed the tank's vacuum space, was defective in that it differed from Chart's intended result, did not conform to Chart's design or specifications, and/or differed from other typical units of the same product line.

43. Tank 4's defects were a substantial factor in causing Plaintiffs' damages, including serious emotional distress, and other harm in an amount to be determined at trial.

SECOND CAUSE OF ACTION
Strict Products Liability – Design Defect

44. In addition or as an alternative to the first cause of action, Chart is strictly liable to Plaintiffs for harm caused by design defects in Tank 4 under California products liability law.

45. Chart manufactured Tank 4, which was defectively designed under the consumer expectations test and/or the risk-benefit test.

Consumer Expectations Test

46. Tank 4 did not perform as safely as ordinary users of cryopreservation tanks expect when used or misused in an intended or reasonably foreseeable way.

47. Tank 4's welding cracked, causing an inner vessel implosion, total vacuum loss, and loss of function. Ordinary users do not expect cryopreservation tanks to suddenly lose their vacuum insulation.

48. Tank 4's failure to perform safely was a substantial factor in causing Plaintiffs' damages, including serious emotional distress, and other harm in an amount to be determined at trial.

Risk-Benefit Test

49. Tank 4's design was a substantial factor in causing Plaintiffs' damages, including serious emotional distress, and other harm in an amount to be determined at trial.

50. In particular, the weld at the liquid nitrogen fill port, which should have sealed the tank's vacuum space, was defectively designed. Among other things, the weld was too thin and the fitting did not sit flush to the tank's inner vessel.

51. Any benefits to its design that Chart may allege in answer to this complaint do not outweigh the risks of the design, taking into account the gravity of the potential harm, the likelihood the harm would occur, the feasibility of an alternative design, the cost of an alternative design, and any disadvantage associated with an alternative design.

THIRD CAUSE OF ACTION
Negligent Failure to Recall

52. Chart acted negligently by failing to recall or retrofit Tank 4 prior to the incident of March 4, 2018.

53. Chart manufactured Tank 4 with a TEC 3000 electronic control system, which could be used to fill the tank with liquid nitrogen, monitor the amount of liquid nitrogen in the tank, and monitor the temperature inside the tank.

54. Chart knew prior to March 4, 2018, that the TEC 3000 electronic control system was prone to malfunction, leading to inaccurate measurements and false alarms.

55. Chart also knew prior to March 4, 2018, and it was reasonably foreseeable, that when the control system malfunctioned, customers would continue to use their cryogenic freezers without a fully functional controller. Sometimes the electronic controller would resume working properly after a while, even though nothing had been done to fix the controller.

56. Chart also knew prior to March 4, 2018, that it was possible for the welds in its freezers to crack, causing an inner vessel implosion, total vacuum loss, and loss of function. Ordinary users, on the other hand, do not expect cryopreservation tanks to implode or suddenly lose their vacuum insulation.

57. Considering what Chart knew about the likelihood of a TEC 3000 electronic controller malfunction and the risks posed by that malfunction, Chart should have recalled or retrofitted all tanks equipped with a TEC 3000 electronic control system prior to March 4, 2018. A reasonable manufacturer faced with the same or similar circumstances would have done so.

58. By failing to recall Tank 4, Chart acted with a willful and knowing disregard of the rights or safety of others, making an award of exemplary damages appropriate.

59. Chart's failure to recall or retrofit Tank 4 was a substantial factor in causing Plaintiffs serious emotional distress and other harm in an amount to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

a. an award of damages in an amount to be determined at trial;

b. prejudgment interest as permitted by law;

c. reasonable attorneys' fees and costs, as permitted for by law; and

d. such other and further relief as the Court deems equitable, just, or proper.

DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury on all issues so triable.

Dated: July 24, 2020

Respectfully submitted,

By: */s/ Adam E. Polk*

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